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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,646	03/15/2002	Kenneth C. Waterman	PC11851AAKM	2293

7590 05/05/2004

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EXAMINER	
CROSS, LATOYA I	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/099,646	WATERMAN, KENNETH C.	
	Examiner	Art Unit	
	LaToya I. Cross	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8-1-02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81. No new matter may be introduced in the required drawing. Applicants' claims 1-21 are directed to a pharmaceutical package. Since the claims are directed to a device, drawings are necessary to help understand the invention.

Claim Observations

- In claim 18, the term "verapamil" is listed for a second time at line 21 of the claim. Applicants should delete the second occurrence of "verapamil".

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 4, 11-15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,682,726 to Green et al.

Green et al teach a package for containing drugs or medicaments wherein the shelf-life

of the drugs is increased. The package comprises a first laminate material (30) that becomes the lid for the package. A second laminate material (32) forms the recess/well in which the drug (100) is contained. A heat-seal coating is provided on laminate (30). The first and second laminate materials are heat sealed to form a reservoir having each individual drug dose (100) sealed therebetween (col. 3, lines 18-45; figure 2. At col. 5, lines 1-7, Green et al teach that an oxygen scavenger (oxygen absorber) may be incorporated into the package to remove oxygen, as recited in claim 1. With respect to claim 4, Green et al teach using sodium metasulfite, a self-activated oxygen absorber. With respect to claims 11, 13 and 18, Green et al teach epinephrine, dobutamine and dopamine as drugs that can be stored in the package. Epinephrine has a pKa of 6.3, as recited in claims 14-15. Green et al further teach a method for forming the package, which comprises forming a reservoir in a first laminate material and dosing the reservoir with a medicament. Next, the reservoir is sandwiched between the first laminate material and a second laminate material and the laminate materials are heat sealed together. Green et al teach that the process is conducted in an inert atmosphere (col. 4, lines 14-30 and col. 5, lines 7-11).

4. Claims 1-5, 7-10, 19-22, 24 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,279,736 to Hekal.

Hekal teaches a barrier pack for storing single doses of medicine, in the form of a tablet, pill or capsule, that provides enhanced protection against contamination. The pack comprises a base portion (10) and a cover portion (20). The base (10) and cover (20) are heat sealed together. A cavity/recess (24) is formed into the cover (20) to contain the pharmaceutical product (4). See col. 3, lines 41-64. A layer having oxygen absorbing capability is also formed

into the package, as recited in claim 1 (col. 2, lines 33-48). With respect to claim 2, Hekal teaches that the absorbing layer is placed between a first layer and a second layer of a three-layer composite (col. 8, lines 57-67). With respect to claim 3, Hekal teaches that the absorbing agent may also be formed into the individual cavities or may be formed into the both the cover composite layers and the cavities (col. 9, lines 4 –24). The oxygen absorbing material is disclosed as being zinc oxide or copper oxide, which may be in the form of powders and which are also moisture-absorbers, as recited in claims 4, 5, 24 and 25. Regarding the method for forming the package, recited in claim 22, Hekal teaches producing a cover portion having at least one cavity/recess, applying an absorbing agent, placing a pharmaceutical product into the cavity and sealing the cover to the base (col. 2, lines 49-57).

With respect to the oxygen absorbing abilities recited in claims 7-10 and 19-21, Hekal teaches the same oxygen absorbers as those claimed (zinc powder and oxygen powder). It is the position of the Examiner that since the oxygen absorbers are same, the properties and the ability to absorb oxygen would be inherent because presumably the oxygen absorbers would have the same properties as those claimed by Applicants. See MPEP 2112.01.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 16, 17, 23, 27-33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hekal in view of Green et al.

The disclosure of Hekal is described above. With respect to conducting the method of forming an oxygen-containing package, Hekal fails to teach conducting the method in an inert atmosphere and the redox potential of the pharmaceutical products.

The disclosure of Green et al is also described above. Green et al teach that when packaging the pharmaceutical product in a blister, the process should be conducted in an inert atmosphere (col. 5, lines 7-11). Green et al also teach that pharmaceutical products such as amines and ephedrine are suitable for being stored in the blister packs. It would have been obvious to one of ordinary skill in the art to conduct the process for forming the pharmaceutical package of Hekal in an inert atmosphere to assure that no substances that will react with the pharmaceutical product will be entrapped in the recess containing the product. Such would also assure that the pharmaceutical products, such as amines and ephedrine, are not contaminated. Further, it would have been obvious to one of ordinary skill in the art that the pharmaceutical products disclosed in Green et al would have redox potentials similar to that recited by Applicants because the pharmaceutical products are known to be sensitive to moisture and oxygen.

8. Claims 6 and 26 rejected under 35 U.S.C. 103(a) as being unpatentable over Hekal in view of US Patent 6,133,361 to Hatakeyama et al.

The disclosure of Hekal is described above. With respect to claims 6 and 26, Hekal fails to teach that the iron oxygen absorber is a hydrogen reduced iron, electrolytically reduced iron, atomized iron or milled pulverized iron powder, as recited in claims 6 and 26. Also, Hekal fails to teach the redox potential values of the pharmaceutical products.

With respect to the iron oxygen absorber, Hatakeyama et al teach oxygen absorbing compositions. Specifically, Hatakeyama et al teach that iron which is reduced, electrolyzed, atomized or mill pulverized are preferable as oxygen absorbers (col. 5, lines 23-37). Thus, it would have been obvious to one of ordinary skill in the art to use reduced, electrolyzed, atomized or mill pulverized iron powders as the oxygen absorbers in Hekal to assure that the package provides optimum oxygen scavenging capability and further assure the integrity of the pharmaceutical product.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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